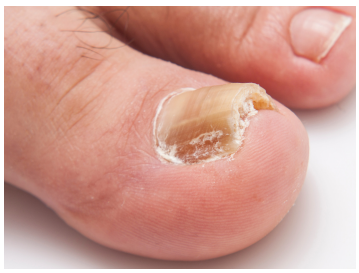
Q4 2020

NailMail

Investor News - Quarterly Activity Report

NailMail is Hexima's regular quarterly newsletter to shareholders, investors and interested parties. If you have any questions or comments you may wish to review our website at www.hexima.com.au.

Onychomycosis (fungal nail infection) and its treatment



Onychomycosis is a fungal nail infection, typically of the toenail, which occurs in approximately 14% of the population. It is more common in the elderly and in males. In the US, 30 million people suffer from this chronic, difficult to resolve infection which causes discolouration and deformation of the toenail, disfiguration, discomfort and in some cases pain and malodour.

While there is a market for over-the-counter (OTC or non-prescription) medications to treat onychomycosis, these products are often regarded as ineffective. Prescription treatments are either oral or topical. Oral prescription treatments suffer from well-documented side effects including rare but serious liver toxicity. Conversely, topical medications are regarded as safer but require daily application for up to 12 months and only deliver a cure in a small percentage of patients.

Hexima

Hexima is a biotechnology company engaged in the research and development of plant-derived defensin peptides for applications as human therapeutics. Our lead product candidate, HXP124 applied in a topical formulation, is a potential new prescription treatment for toenail fungal infections (or onychomycosis).

Hexima is currently conducting an Australian phase IIb clinical trial of HXP124 for onychomycosis. Hexima holds granted, long-life patents protecting HXP124 in major markets globally.

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HXP124 potential as a treatment for onychomycosis

Hexima believes HXP124 addresses the important short comings of available treatments for onychomycosis. It is a broad spectrum and powerful antifungal agent which penetrates nails very rapidly when applied topically. It is safe and well tolerated and in a recent clinical trial demonstrated:

- **Short course of therapy:** HXP124 appears active following just 6-weeks of daily therapy
- **More effective**, clearing fungus from the nail two-times more effectively than current best-in-class (oral and topical) products at the same time point - 52% mycological cure
- **Fast acting**, started to improve the appearance of the infected nail within 12 weeks - 19.5% clinical efficacy (<10% infected nail area)
- **Safe and well tolerated**, with no treatment area irritation or treatment-related adverse events·
- **Locally acting**, HXP124 effectively penetrates nails but is not detected in the blood stream and has not presented any systemic toxicity

This is a consumer driven market and based on our market research, there is a well-defined and under-served demand from consumers (clinicians and their patients) who are looking for such features in their treatment.

Important developments and milestones in Q4 2020

Study initiation and first patient treated: During the quarter, the first patient was treated in our Australian phase IIb clinical trial. 10 clinical sites in Australia and New Zealand are now active and recruiting patients.

Coronavirus lockdowns: Like many businesses in Australia ours has seen an impact from the Coronavirus. Specifically, the pace of enrolment of patients into our phase IIb trial has been modestly impacted by State travel restrictions, business closures and mandated lock downs due to the Coronavirus pandemic. These events have not affected in any way the integrity of the trial but are likely to result in data from the clinical trial being available in the second quarter of 2022.

Mitigating the effects of Lockdowns: Hexima has recently added additional clinical investigator sites and adopted other measures to accelerate patient recruitment and enrolment.

Cash balance as of 31 December 2020: Following a successful private placement earlier in the year, Hexima completed a public offer and listing on ASX on 1 December 2020. Hexima also received an R&D Tax Incentive rebate of $1.9 million and finished the year with $7.58 million in the bank. Importantly Hexima holds adequate capital to fund its ongoing phase IIb clinical trial and deliver results which, if positive, would validate the potential of HXP124 as a new and attractive treatment for onychomycosis.

Manufacture scale-up: Manufacture scale-up activities commenced in Q4 2020 and are progressing according to plans.

Use of funds during the quarter ended 31 December 2020 was consistent with Hexima's expectations set out in its Prospectus dated 15 October 2020 and filed with ASIC, with the exception of a lower level of expenditure on its phase IIb clinical trial as a direct result of the impact of Coronavirus lockdowns as described above.

Milestones to look forward to in 2021

2021 is an important year for Hexima. We expect our phase IIb clinical trial to deliver results which will validate the potential for HXP124 to exhibit the product features of a new and attractive treatment for onychomycosis.

Progress in our clinical trial is defined by some well-established milestones:

- **First patient treated**: achieved in October 2020
- **Completion of enrollment**: expected by end of Q2 2021
- **Clinical trial results**: expected by end of Q2 2022

In addition to clinical trial activities, we expect important progress on manufacturing scale-up and toxicology studies to support our goal of filing an Investigational New Drug (IND) Application with FDA, ahead of initiating our planned phase III program in the US.

These are critical development steps towards approval of a new therapeutic product. We have been pleased to see the uptick in patient recruitment following the steps we have taken to address the Coronavirus related slow down. We look forward to keeping our shareholders informed of our progress.